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Citation

Michael Ricci, Trends in the Regulation of Genetically Modified Products in the European Union from 1990 to the Present (April 2010).

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Trends in the Regulation of Genetically Modified Products in the European Union from 1990 to the Present

Michael Ricci
Class of 2010
April 5, 2010

This paper is submitted in satisfaction of the course requirement.

Abstract

The EU took its first steps towards regulation of genetically modified organisms and products in 1990. Over the next twenty years, the EU's regulatory approach evolved to impose greater regulatory burdens on genetically modified products and to mandate ever greater disclosure to member states, EU institutions and to the ultimate consumers of these genetically modified products. As experience under the earlier regulatory initiatives accumulated, it became apparent that member state discretion frustrated the operation of a common approach to genetically modified products at the European level. In response to these shortcomings, centralization of regulatory authority in the hands of EU institutions proceeded apace, with the result that the Commission now drives the approval process for genetically modified products. This paper traces and analyzes these changes in EU regulation of genetically modified products over time.

Introduction

The regulation of genetically modified (GM) organisms at the European level has changed a great deal since its inception in the early 1990s. Starting out from a relatively decentralized approach based on directives instructing member states to achieve certain regulatory ends, the trend in EU regulation of GM products has been toward ever greater centralization of decision-making authority in EU-level institutions. The regulatory burden on GM products has also increased, with more detailed risk assessments and disclosure requirements being imposed by successive directives and regulations. The end result of this regulatory development is a quite intrusive pre-market approval system for GM products that

incorporates the precautionary principle and the consumers' right to know when they are consuming GM products, and places EU institutions at the center of the approval process.

The EU Council of Ministers adopted two directives in 1990, marking the first major attempt at regulating GM organisms at the EU level.¹ Under EU law, a directive is a measure that is binding on the individual EU member states as to the result to be achieved, but leaves to the member states the choice about how to go about achieving that objective, with the result that harmonization of policies can be fostered without forcing agreement on the particulars of small details of implementation.² Directive 90/219 EEC covers the contained use of GM micro-organisms.³ Directive 90/220 EEC governs the deliberate release into the environment of GM organisms.⁴ From its very inception, the EU's regulation of GM products made a distinction between contained uses and uses that are expected to have a broader impact, whether through release into the environment or into the market. Both of these directives distinguish GM organisms from non-GM organisms according to the process of modification they have undergone – with parallel annexes (Annex I A Part 1 in both directives) specifying certain techniques of genetic modification that will subject an organism to regulation, including recombinant DNA techniques.⁵

Directive 90/219

Directive 90/219 EEC sets up a regulatory structure to deal with contained uses of GM micro-organisms. While it has been amended over the years, principally by Directive 98/81 EC,

¹ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 58.

² Bernd van der Meulen and Menno van der Velde, Food Safety Law in the European Union: An Introduction, (Wageningen Academic Publishers 2004), pp 84-85.

³ Council Directive 90/219, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 1-14.

⁴ Council Directive 90/220, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 15-27.

⁵ Council Directive 90/219 and Council Directive 90/220, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 7, 22.

its amended form continued in force until it was repealed in May 2009 by Directive 2009/41 EC (though this repeal was more in the nature of recasting it in the interests of clarity).⁶ A “contained use” is any operation that genetically modifies a micro-organism or one that stores, transports, uses, destroys or otherwise disposes of such GM micro-organisms, so long as there are physical barriers or a combination of physical and chemical/biological barriers that limit the contact between the organism and the general population and environment.⁷ For such contained uses, the user must carry out a prior risk assessment of the contained uses with respect to human health and the environment, and must make this risk assessment available to the competent member state authorities as part of any required notifications.⁸ Annex III outlines the safety assessment parameters, among them the characteristics of the donor and modified organisms, and, more interestingly, a number of health and environmental considerations. The health considerations include toxic and allergenic effects and pathogenicity. The environmental considerations include how this modified micro-organism might fit into habitats in the broader environment and available techniques for detecting and monitoring the micro-organism and transfers of genetic material from the micro-organism.⁹

In addition to this required risk assessment, Directive 90/219 essentially establishes a two-track process for approval of contained uses. Annex II divides GM micro-organisms into two groups – Group I (which can be conceived of as “safe” micro-organisms) and Group II (which is a catch-all category for all GM micro-organisms that do not meet the criteria for

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0219:EN:NOT>, last accessed on March 25, 2010 (lists the amendments/changes to Directive 90/219 EEC).

⁷ Council Directive 90/219, art. 2, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 2

⁸ Council Directive 90/219, art. 6, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 3

⁹ Council Directive 90/219, annex III, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 9-10.

inclusion in Group I).¹⁰ Contained uses of both Group I and Group II micro-organisms must be notified to the competent member state authority, but under Article 11 the contained uses of Group I micro-organisms are generally allowed to proceed in the absence of a contrary indication within 60 or 90 days, while certain of the contained uses of Group II micro-organisms require the affirmative consent of the competent authority before the use may proceed.¹¹ In this way, Directive 90/219 creates what may be thought of as a “true” prior notification process for safer GM organisms, with the reservation of a prior approval process for contained uses of GM organisms that do not fit with established safety criteria.

The decision-making authorities contemplated by Directive 90/219 are national authorities designated by member states under Article 11. The institutions of the EU and its other member states must be kept informed and consulted in the event of accidents, but the individual member state makes the decision on the contained use.¹² The localized nature of this decision-making contrasts with the more collective decision-making procedures created under Directive 90/220, and was perhaps decided upon because contained uses pose a lesser risk of the sort of cross-border problems that a deliberate introduction of GM organisms into the environment or the market might be expected to cause.

Though the general regulatory scheme established for contained uses in Directive 90/219 has continued in force, there have been several notable amendments, in particular those imposed by Directive 98/81 EC. Directive 98/81 refines the risk assessment that a proposed user must undertake, mandating that the assessment result in a final classification of the contained uses into

¹⁰ Council Directive 90/219, annex II, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 8.

¹¹ Council Directive 90/219, art. 8-11, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 8.

¹² Council Directive 90/219, art. 11, 16, 18, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 4-5.

four classes of ascending risk, which are assigned according to the appropriate level of containment procedures.¹³ These classes of risk replace the Group I and Group II classifications from Directive 90/219 and the two systems of pre-use notification and pre-use approval are applied to these classes. Classes 1 and 2 fall within the pre-use notification system, while Classes 3 and 4 fall within the pre-use approval system, with the main change being a much more elaborate system of containment procedures being applied to these classes by Annex IV.¹⁴ Directive 2009/41 EC (which replaced both earlier directives) essentially retained the changes that Directive 98/81 made to Directive 90/219.¹⁵

These amendments result in a more intrusive regulatory regime, with containment procedures detailing, for example, whether specific measures to control aerosol dissemination are necessary (it is required to use measures to minimize it at containment level 2, to prevent it at containment levels 3 and 4, but no measures are required at containment level 1).¹⁶ Compared to the earlier Directive 90/219, the amendments of Directive 98/81 represent a step from harmonization of risk assessment (which is still retained and refined under the amendments) towards greater harmonization of risk management, as represented by the addition of detailed containment procedures. Recall that a directive under EU law is binding on EU members as to the end to be achieved but not as to the means to achieve it.¹⁷ In the move from Directive 90/219 to the amendments of Directive 98/81, the end to be achieved became much more clearly defined, especially with respect to risk management, which in turn narrowed the scope of member state

¹³ Council Directive 98/81, art. 5-6, 1998 Official Journal of the European Communities L330 of 05/12/1998, pp. 15.

¹⁴ Council Directive 98/81, art. 7-10, annex IV, 1998 Official Journal of the European Communities L330 of 05/12/1998, pp. 15-16, 23-29.

¹⁵ Directive 2009/41 of the European Parliament and of the Council, 2009 Official Journal of the European Union L125 of 05/21/2009, pp. 75-92.

¹⁶ Council Directive 98/81, annex IV, 1998 Official Journal of the European Communities L330 of 05/12/1998, pp. 24.

¹⁷ Bernd van der Meulen and Menno van der Velde, Food Safety Law in the European Union: An Introduction, (Wageningen Academic Publishers 2004), pp 84-85.

discretion as to appropriate means. In the regulation of contained uses of GM micro-organisms, therefore, there has been a trend towards greater regulatory harmonization at the EU level with respect to both risk assessment and risk management.

Directive 90/220

Directive 90/220 EEC sets up a regulatory structure to deal with the deliberate release of GM organisms into the environment and the market. The directive defines “deliberate release” to mean the “intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment” such as physical or a combination of physical and biological/chemical barriers.¹⁸ This definition of “deliberate release” carves out the contained uses that are subject to Directive 90/219 by excluding GM organisms provided there are provisions for containment. Having established a regulatory structure bifurcated between contained uses and deliberate release, Directive 90/220 goes on to make clear that its provisions apply to two separate situations – the first is the deliberate release of GM organisms into the environment for purposes other than placing them on the market, and the second is the placing of products containing or consisting of GM organisms on the market.¹⁹

Articles 5 through 9 of Directive 90/220 govern the deliberate release of GM organisms into the environment. Essentially, these Articles provide that the intended releaser of a GM organism must give a “notification” to the competent authority of the member state in which the release will take place.²⁰ The notification for deliberate release under Directive 90/220 resembles that under Directive 90/219, and consists of a detailed technical dossier containing

¹⁸ Council Directive 90/220, art. 2, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 16.

¹⁹ Council Directive 90/220, art. 1, 5-18, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 16-20.

²⁰ Council Directive 90/220, art. 5, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 17.

specified information relevant to evaluating the risk of the GM organism to the environment and human health along with a statement regarding impacts and risks posed to human health and the environment. The main difference lies in the fact that Directive 90/220 goes into much greater detail about the information that must be included, especially with respect to the potential environmental impact.²¹ Unlike Directive 90/219 which created two systems of “notification” – one requiring pre-use approval and the other merely requiring pre-use notice, in order to proceed with a deliberate release under Directive 90/220 the notifying party must have received written consent from the competent member state authority.²² Though it is labeled a “notification” system, the regulations governing the deliberate release of GM organisms actually require an application be made for the right to release, which the competent authority may grant or deny according to certain criteria. The competent authority has discretion to make its decision to accept or reject the application based upon whether the notification complies with Directive 90/220, but the competent authority is also asked to evaluate the risks posed by the release,²³ which would seem to permit the competent authority to use its own independent risk assessment as a basis for deciding on the application. As under Directive 90/219, the relevant decision-making actor under the deliberate release sections of Directive 90/220 is the competent authority of the individual member state whose territory is directly affected. The other member states and EU-level institutions have the right to receive information about but no right to formally participate in the final decision regarding deliberate release.²⁴

²¹ Council Directive 90/220, art. 5, annex II, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 17, 23-27.

²² Council Directive 90/220, art. 6, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 18.

²³ Council Directive 90/220, art. 6, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 17-18.

²⁴ Council Directive 90/220, art. 6, 9, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 17-18.

Articles 10 through 18, together with Article 21, of Directive 90/220 lay out the regulatory framework governing the placing on the market of products containing or consisting of GM organisms. Release of a product containing or consisting of GM organisms can take place only after consent has been received from the competent authority of the member state in which the product will be placed on the market for the first time.²⁵ Article 10 makes clear that consent may only be given if, among other requirements, written consent has already been given to a notification with respect to deliberate release into the environment under Articles 5 through 9, or if a risk analysis has been carried out based on the elements outlined in those Articles.²⁶ The provisions governing release into the market therefore build upon the provisions governing release into the environment – the required risk assessment for release into the environment is made a necessary, but not sufficient, prerequisite for consent to market release.

Article 11 imposes further requirements for consent, most notably an expanded notification requirement. All the information necessary in a notification for release into the environment is required, to be supplemented with further information when necessary after taking into account the diversity of “sites and uses” of the product along with information derived from research and developmental releases of the product.²⁷ The implication is that release into the market is expected to be of wider geographic scope than release into the environment. Deliberate release into the environment provides an opportunity to investigate effects on human health and the environment, the results of which an applicant in the market notification procedure would do well to provide to the competent authority. Each new product, even if it contains the same GM organism or combination of such organisms, must submit a

²⁵ Council Directive 90/220, art. 11, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 19.

²⁶ Council Directive 90/220, art. 10, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 18.

²⁷ Council Directive 90/220, art. 11, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 18-19.

separate notification for its different intended uses.²⁸ A notification must also include a proposal for packaging and labeling, which should include the name of the product and the names of the GM organisms contained therein.²⁹ The importance of this proposal for packaging and labeling is magnified by the fact that Article 14 requires that member states “take all necessary steps to ensure that products...containing GMOs will be placed on the market only if their labelling and packaging is that specified in the written consent.”³⁰ Article 14 can therefore be read to require some labeling of GM products before they are put on the market, with the contents of this labeling left, at the first instance, to the proposal by the applicant (ultimately the need to obtain consent will constrain the applicant’s discretion in proposing its labeling). As it has been interpreted however, Article 14 and Annex III were not read to require labeling for products approved “in the absence of safety reasons.”³¹

Under Article 12, the competent authority of the member state who receives the application may either forward the dossier with a favorable opinion to the Commission or reject the application.³² If the competent authority decides to reject the application, then the decision-making procedure ends and the product will not be permitted to be released into the market.³³ If however, the competent authority forwards the dossier with a favorable opinion, then a new decision-making procedure commences that opens up involvement in the decision-making process to EU-level institutions and the other EU member states. The Commission forwards the dossier to the competent authorities of all the member states, who have 60 days to decide

²⁸ Council Directive 90/220, art. 11, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 19.

²⁹ Council Directive 90/220, art. 11, annex III, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 19, 27.

³⁰ Council Directive 90/220, art. 14, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 20.

³¹ Erika Meins, Politics and Public Outrage: Explaining Transatlantic and Intra-European Diversity of Regulations on Food Irradiation and Genetically Modified Food, (Lit Verlag 2003), pp. 120.

³² Council Directive 90/220, art. 12, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 19.

³³ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 61.

whether to raise an objection.³⁴ If no such objection is raised, then the competent authority of the member state who initially received the application may give written consent to the proposed release into the market.³⁵ If, however, an objection is raised, then the decision-making procedures of Article 21 are invoked. Under these procedures, the Commission undertakes its own assessment and delivers a draft decision (which could be for acceptance or rejection of the application) to a committee composed of representatives of the member states.³⁶ If the committee accepts the Commission's decision, then the written consent may be given. If the committee does not accept the Commission's decision or does not deliver an opinion at all, then the Commission's decision is submitted to the Council of Ministers for approval – the Council of Ministers can accept the Commission decision with a qualified majority vote and can also reject the Commission decision – again requiring a qualified majority vote.³⁷ If the Council has not reached a decision one way or the other within 3 months, Article 21 authorizes the Commission to adopt the measures that it had initially proposed.³⁸

This is the first point in our sketch of EU regulation on GM organisms that we see a decision being taken away from an individual member state and being made subject to a community-based decision-making procedure. The level of political involvement in the approval process is notable – politicians enacted the regulatory framework contained in Directive 90/220, the Commission (composed of political officials appointed by the member states) makes the draft

³⁴ Council Directive 90/220, art. 13, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 19.

³⁵ *Id.*

³⁶ Council Directive 90/220, art. 21, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 21.

³⁷ Simonetta Zarelli, International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks, Policy Issues in International Trade and Commodities Study Series No. 29, UNCTAD, United Nations Publication, 2005, pp 10 footnote 26; *But See* Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 62. (Pollack and Shaffer take the view that the Council can only act to reject the Commission's draft decision with a unanimous vote – as the sources differ, I included the information in the body of the paper that appears to be the best interpretation of the Directive's text.).

³⁸ Council Directive 90/220, art. 21, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 21.

decision in the event of member state objection, and the Council of Ministers (again composed of member state politicians) takes a vote on whether to approve the Commission decision.³⁹ In fact, the legislative history of Directive 90/220 supports the proposition that the member states desired to increase their own control over the regulatory process at the expense of the Commission's power. The initial Commission draft of what, in altered form, became Directive 90/220 contained only an advisory committee whose opinion the Commission would have to consider, with ultimate decision-making authority remaining with the Commission, but this was replaced in its final version by a committee with power to vote up or down the Commission proposal.⁴⁰ In multiplying the points in the regulatory process where politically-motivated actors can get involved, the regulatory structure created by Directive 90/220 appears designed to subject the approval procedure for GM products to popular democratic pressures. Though perhaps more democratic in this sense, Directive 90/220 may be criticized on the grounds that regulation is being channeled through a political, rather than a "purely administrative" process,⁴¹ and thus there may be pressures to depart from regulation that is scientifically justified and technocratically administered.

One final feature of Directive 90/220 that bears mentioning is the safeguard clause built into Article 16 whereby a member state may, upon giving "justifiable reasons" to the Commission and other member states, provisionally restrict or prohibit the use or sale of a GM product which had already received a written consent allowing that product to market.⁴² If a member state introduces such a safeguard measure, the Article 21 procedures come into play,

³⁹ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 62.

⁴⁰ *Id.* at, pp 61-62.

⁴¹ *Id.* at pp 64.

⁴² Council Directive 90/220, art. 16, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 20; Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 62.

with the Commission making an initial decision which then goes to the committee and then, if necessary, the Council decides by qualified majority whether to accept or reject such decision within 3 months. Article 16 provides a means by which previously resolved regulatory disputes may be revived by recalcitrant member states, with potentially unfortunate consequences for the stability of the regulatory regime and the settled expectations that would otherwise be protected by it.

Directive 90/220 continued in effect until it was repealed and replaced by a new directive on deliberate release – Directive 2001/18. During the time that it was in effect, eighteen GM products were approved for market release under Directive 90/220.⁴³ The majority of these approved products were GM plants – tobacco, maize, swede rape, soyabeans, chicory, and carnations, but there were also three vaccines and a test kit to detect anti-biotic residues in milk.⁴⁴ The first of these consents to marketing a GM product under Directive 90/220 took place in 1992, while the last consent was given in 1998.⁴⁵ From 1998 to 2004, no GM products were approved under Directive 90/220 or its successor Directive 2001/18.⁴⁶ This so-called “moratorium” on approval of GM products first found expression through the use of safeguard bans, which were permitted under Article 16 of Directive 90/220.⁴⁷ By 2001, 8 member state safeguards were in effect, imposed by Austria, France, Germany, Greece and Luxembourg – these safeguards were targeted at certain GM variants of maize and oil seed rape.⁴⁸ In 1999, a group of 5 member states announced that, until the adoption of a new regulatory framework at

⁴³ Brian Sheridan, EU Biotechnology Law & Practice, (Palladian Law Publishing Ltd. 2001), pp. 62.

⁴⁴ *Id.* at 63-64.

⁴⁵ *Id.* at 63-64.

⁴⁶ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 68.

⁴⁷ *Id.* at 66-67.

⁴⁸ Brian Sheridan, EU Biotechnology Law & Practice, (Palladian Law Publishing Ltd. 2001), pp. 81.

the EU level to govern the market introduction of GM products, they would take steps to suspend authorizations for the release of GM organisms into the market.⁴⁹

The regulatory design choices reflected in Directive 90/220 facilitated this de facto moratorium. The permissive approach to safeguards under Article 16 along with the politicization of decision-making through the introduction of the Council as a decision-maker in contested applications under Article 21 gave scope to the operation of interested political actors who could be subjected to democratic pressures from national member state populations. It was probably not a foregone conclusion at the time of the adoption of Directive 90/220 that public perception would swing against GM organisms. However, once exogenous shocks to public perceptions of the safety of the food supply occurred (the mad cow disease scare in 1996 is an example⁵⁰), the popular backlash against GM organisms could feed into the regulatory apparatus through the aforementioned Articles in Directive 90/220. The resulting alliance between a dominant public opinion and certain member states at the EU level may be seen as producing a sort of path dependence that operates to prevent the EU from loosening its regulatory regime with respect to GM organisms.

Regulation 258/97

Despite the imposition of the moratorium, there remained one regulatory route under which GM food products were being approved in the period from 1998 to 2004. Regulation 258/97 EC, which came into force in 1997, covers novel foods and food ingredients and provides a regulatory path for introduction of these foods to the market. For present purposes, Regulation 258/97 is applicable both to food and food ingredients (1) containing or consisting of GM

⁴⁹ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press, 2009), pp 67-68.

⁵⁰ *Id.* at 64.

organisms and to those (2) produced from but not actually containing GM organisms.⁵¹ Food and food ingredients produced from but not containing GM organisms were not covered by Directive 90/220, which addressed only products containing or consisting of GM organisms.⁵² By its terms, Regulation 258/97 exempts products that are food and food ingredients containing or consisting of GM organisms from Articles 11 through 18 of Directive 90/220, which govern the application for market approval, instead making these products subject to the requirements of Regulation 258/97.⁵³ Foods and food ingredients subject to Regulation 258/97 must meet three main substantive requirements: they must not harm the consumer, they must not mislead the consumer, and they must not differ from foods or food ingredients that they are intended to replace if this difference will result in nutritional disadvantage to the consumer under conditions of normal consumption.⁵⁴ In most respects these requirements are, or at least could have been, incorporated under the procedures for authorization under Directive 90/220, but Regulation 258/97 goes further in making them independent substantive requirements which apply outside of any authorization procedure. Directive 90/220 did not, however, have the requirement of not creating a nutritional disadvantage. Regulation 258/97 goes further than Directive 90/220 both because it directly imposes these three substantive requirements and because it extends the scope of regulation to cover new products that were not previously subject to regulation. However, products containing or consisting of GM organisms and those merely produced from GM organisms are potentially subjected to very different procedures for admission to the market.

⁵¹ Regulation 258/97 of the European Parliament and of the Council, art. 1, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 2.

⁵² Council Directive 90/220, art. 2, 10, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 16, 18.

⁵³ Regulation 258/97 of the European Parliament and of the Council, art. 9, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 5.

⁵⁴ Regulation 258/97 of the European Parliament and of the Council, art. 3, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 3.

Regulation 258/97 creates two procedures for approval of novel foods and food ingredients – a general authorization procedure under Article 6 and a special notification procedure under Article 5 applying only to specific groups of novel foods and food ingredients.⁵⁵ Under Article 3(4) the special notification procedure may be available to foods and food ingredients produced from but not containing GM organisms.⁵⁶ In order to qualify for the notification procedure, these products, based either upon scientific evidence and generally recognized as such or based on an opinion delivered by a competent body of a member state, must be substantially equivalent to existing food/ingredients in terms of composition, nutritional value, metabolism, intended use, and level of undesirable substances within them.⁵⁷ The exact meaning of substantial equivalence has not been fully defined in EU law.⁵⁸ Despite the potential vagueness of its application, the special notification procedure allows qualifying novel food or food ingredients to avoid the general authorization procedure and to be placed on the market at the same time that notification is delivered.⁵⁹ The decision to make products produced from but not containing GM organisms eligible for relaxed regulatory treatment appears to go against the general trend of increasing stringency of regulation with respect to GM products. While the concept of substantial equivalence represented a possible opening towards a more relaxed regulatory approach, this approach remained confined to the limited application seen in Regulation 258/97. The regulatory approach under Directive 90/220 covering products containing or consisting of GM organisms remained in place, unaffected by the limited introduction of this concept of substantial equivalence.

⁵⁵ Regulation 258/97 of the European Parliament and of the Council, art. 3, 5, 6, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 3-4.

⁵⁶ Regulation 258/97 of the European Parliament and of the Council, art. 3, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 3.

⁵⁷ *Id.*

⁵⁸ Brian Sheridan, EU Biotechnology Law & Practice, (Palladian Law Publishing Ltd. 2001), pp. 143, 145.

⁵⁹ *Id.* at 142-143.

The general authorization procedure for GM foods and food ingredients resembles that set out under Directive 90/220. The complete technical dossier with all of the required information under Article 11 of Directive 90/220 is still required as just one part of an application under Regulation 258/97.⁶⁰ After a request containing the required information, including the aforementioned technical dossier is filed, the member state that received the request will conduct an initial assessment.⁶¹ The purpose of the initial assessment is to decide whether to require an additional assessment of the novel food or food ingredient.⁶² Other member states have an opportunity to raise objections after the initial assessment report is distributed to them. If the initial member state decides an additional assessment is necessary, or if another member state raises an objection to the initial assessment report, then the same basic decision-making process seen under Article 21 of Directive 90/220 applies.⁶³ The Commission drafts a proposal for consideration by a committee, with the matter being referred for decision by a qualified majority vote of the Council if the committee disagrees or does not issue a decision.⁶⁴ The main differences in the decision-making procedure are that Regulation 258/97 specifies the Standing Committee on Foodstuffs as the committee that will consider the Commission's proposal and that the member state which issues the initial assessment does not have the authority to kill the application – it must forward its negative assessment, thereby triggering the Article 13 Committee-Commission-Council process.⁶⁵

⁶⁰ Regulation 258/97 of the European Parliament and of the Council, art. 9, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 5.

⁶¹ Regulation 258/97 of the European Parliament and of the Council, art. 6, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 4.

⁶² *Id.*

⁶³ Regulation 258/97 of the European Parliament and of the Council, art. 7, 13, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 4, 6.

⁶⁴ Regulation 258/97 of the European Parliament and of the Council, art. 13, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 6.

⁶⁵ *Id.*

The provisions of Regulation 258/97 also introduce new labeling requirements. These labeling requirements apply to both products consisting of or containing GM organisms and those merely produced from such organisms.⁶⁶ Labels must disclose when a GM organism is present, when the novel food/ingredient may give rise to health or ethical concerns, and when a food property, such as composition or nutritional value, differs such as to make the novel food no longer equivalent to its existing food comparison (and to provide disclosure on its nature if no such comparison exists).⁶⁷ The labeling regime under Regulation 258/97 lays out the requirements for disclosure in more detail than Directive 90/220, which largely left the labeling requirements to be imposed in the application process. While admittedly more intrusive, the move towards standardization of required information in labeling represents a step forward from the more case-by-case approach under Directive 90/220 since consumers will be better able to compare products when faced with identical labeling requirements and producers stand to be treated more equally and experience greater predictability in the regulation of labeling.

Article 12 of Regulation 258/97 retains a safeguard clause allowing member states to restrict or suspend market access for food or food ingredients admitted to the market under the Regulation. While this safeguard clause does not appreciably limit the scope of the application of safeguards, it does clarify what information will be sufficient to justify them. While Directive 90/220 called for “justifiable reasons” for finding risks to human health or the environment,⁶⁸ Regulation 258/97 requires “detailed grounds,” based on new information or a reassessment of existing information, showing that the food or food ingredient “endangers” human health or the

⁶⁶ Regulation 258/97 of the European Parliament and of the Council, art. 5, 8, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 4-5.

⁶⁷ Regulation 258/97 of the European Parliament and of the Council, art. 8, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 5.

⁶⁸ Council Directive 90/220, art. 16, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 20.

environment.⁶⁹ The change in language to require that a safeguard be based on new information or a reassessment of existing information is meaningless – all information will fall into one or the other category. The shift from being able to impose a safeguard when a product constitutes a risk to being able to impose a safeguard when human health or the environment are actually being endangered might be seen as a shift in the standard according to which a safeguard ought to be judged, but given that the procedure for declaring a safeguard and having it evaluated by the Commission is unchanged, the shift in language does not increase the Commission's ability to prevent safeguards from being declared.

The regulatory regime established under Regulation 258/97 experienced relative success after its adoption. According to the EU's list of authorized products, from 1997 to 2002 fourteen GM foods and food ingredients were allowed on the EU market under Regulation 258/97, predominantly varieties of oilseed rape, maize and even cotton.⁷⁰ How did all these GM foods and food ingredients gain access to the market while there was a de facto moratorium imposed by a number of recalcitrant member states? The answer lies in the Article 5 notification procedure under Regulation 258/97 which permitted substantially equivalent food and food ingredients on the market after notification was made. All of the varieties of GM food and food ingredients approved in the period from 1997 to 2002 came about under the Article 5 process.⁷¹ It was only after the moratorium ended in 2004 that the Article 7 procedure was successfully used to get a GM food or food ingredient on the market.⁷² Though Regulation 258/97 functioned

⁶⁹ Regulation 258/97 of the European Parliament and of the Council, art. 12, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 6.

⁷⁰ "Genetically Modified (GM) Foods Authorized in the European Union under the Novel Food Regulation (EC) 258/97," found at: http://ec.europa.eu/food/food/biotechnology/authorisation/258-97-ec_authorisated_en.pdf, last accessed on March 25, 2010.

⁷¹ *Id.*

⁷² *Id.*

to allow some GM products on the market, it would take further legislation at the EU level to satisfy the member state demands that lay behind the institution of the moratorium.

Directive 2001/18

Directive 2001/18 EC replaces the prior Directive 90/220 EC on the subject of deliberate release into the environment of GM organisms. Directive 2001/18 largely retains the regulatory structure put in place by Directive 90/220. There are still different regulatory approval tracks for deliberate release into the environment and release of a product onto the market, with the former being handled by the competent authority of the concerned member state and the latter being governed by a decision-making process that splits authority between the Commission and the Council. Despite the broad similarities between Directive 2001/18 and Directive 90/220, there are a number of important changes that bear mentioning.

Directive 2001/18 makes numerous references to the precautionary principle, a principle which is never mentioned in the earlier Directive 90/220. Article 1 makes the Directive's objective of protecting human health and the environment subject to the precautionary principle.⁷³ Article 4 imposes a general obligation on member states to act in accordance with the precautionary principle to take all appropriate measures to protect human health and the environment from risks created by deliberate release of GM products.⁷⁴ Finally, Annex II states that the precautionary principle should be followed as a general principle when conducting the environmental risk assessment.⁷⁵ The precautionary principle may thus be seen as suffusing both

⁷³ Directive 2001/18 of the European Parliament and of the Council, art. 1, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 4.

⁷⁴ Directive 2001/18 of the European Parliament and of the Council, art. 4, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 5.

⁷⁵ Directive 2001/18 of the European Parliament and of the Council, annex II, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 19.

the risk assessment (Annex II) and the risk management (Article 4) obligations imposed by the Directive, in addition to forming part of the objective (Article 1) to which the Directive is directed and according to which it will be interpreted. Directive 2001/18 thus accepts the precautionary principle, signaling an open embrace of a precautionary approach to regulation,⁷⁶ an embrace that was not fully discernible in the earlier Directive 90/220. The incorporation of the precautionary principle might be understood as an attempt to build the primary justification underlying the regulation of GM organisms into the regulatory scheme itself and make the strict regulations it imposes more internally defensible, given that the EU's regulation in this field had come under increasing fire, particularly from the U.S., with the possibility of a WTO dispute looming large.⁷⁷ At the very least, Directive 2001/18 reveals how a regulatory regime may grow over time to incorporate justifications for its own perpetuation that were not fully in existence at the time of its creation.

Another major philosophical change came in the form of a much greater focus on transparency and the public's right to know. In considering whether to consent to a notification for deliberate release into the environment, the competent member state authority is directed to "consult the public, and, where appropriate, groups."⁷⁸ As previously noted, Directive 90/220 already gave great scope to the public to act through the democratic process upon their elected representatives and thereby indirectly influence the regulatory decision-making with respect to GM organisms. Directive 2001/18 takes this one step further, bringing the public and civil society directly into the decision-making process, albeit without any real decision-making

⁷⁶ Lee Ann Patterson and Timothy E. Josling, Regulating Biotechnology: Comparing EU and US Approaches; (European Policy Paper No. 8, European Union Center, Center for West European Studies at the University of Pittsburgh University Center for International Studies 2002), pp. 3.

⁷⁷ See Lucia La Rosa-Ames, The European Union's Laws on Genetically Modified Foods – Issues of Consistency with World Trade Organization Rules, ([No publisher information, borrowed from Harvard Law School International Legal Studies Library] 2003), pp 3, 11.

⁷⁸ Directive 2001/18 of the European Parliament and of the Council, art . 9, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 8.

authority. Nevertheless, Directive 2001/18 demonstrates a trend toward greater democratization of the regulatory regime governing GM organisms. Article 24 also creates a mandatory requirement that the Commission disseminate certain information to the public upon its receipt of a dossier after an application has been made to put a GM product on the market.⁷⁹ This movement towards greater transparency may also be seen in the increased emphasis on labeling. Following earlier amendments to Directive 90/220 contained in Directive 97/35 EC, Directive 2001/18 requires that a GM product introduced to the market must be labeled with words to the effect that “this product contains genetically modified organisms.”⁸⁰ Directive 2001/18 opens the possibility, though, that a minimum threshold below which labeling will not be required might be established for products in which there are “adventitious or technically unavoidable traces of authorized GMOs.”⁸¹ Taken together, the provisions calling for consulting and sharing information with the public (through labeling and otherwise) demonstrate a shift in the regulatory structure towards recognition and accommodation of consumers’ right to be informed and to decide whether they wish to consume GM products. In this sense, Directive 2001/18 articulates a further justification for the regulatory regime initially imposed by Directive 90/220.

Directive 2001/18 also tightened up the safeguard clause, which member states had been using rather loosely to block introduction of previously approved GM products to their markets, in turn undermining the integrity of the common market and the legitimacy of the collective decision-making process used to make approvals. Under the old safeguard clause, a member state was permitted to impose a safeguard measure when it had “justifiable reasons” to consider

⁷⁹ Directive 2001/18 of the European Parliament and of the Council, art. 24, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 14.

⁸⁰ Directive 2001/18 of the European Parliament and of the Council, art. 21, annex IV, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 13, 32-33.

⁸¹ Directive 2001/18 of the European Parliament and of the Council, art. 21, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 13.

an already approved product a human health or environmental risk.⁸² Under the new safeguard clause, a member state is only permitted to introduce a safeguard measure when, on the basis of new or additional information or scientific knowledge, it has “detailed grounds” for considering the GM product a human health or environmental risk.⁸³ The new safeguard clause imposes at least some small amount of additional discipline upon member state discretion, prompting the member state to explain its safeguard decision solely on the basis of new information and knowledge in the context of the previously approved environmental risk assessment.⁸⁴ While this reform to the safeguard process appears small, it represented one small step toward closing one of the largest loopholes in the prior Directive 90/220.

Directive 2001/18 also made several important reforms by tinkering around the edges of the notification and approval process. The notification process for both deliberate release into the environment and introduction to the market was “enhanced to include a more extensive environmental risk assessment” than had been required under Directive 90/220.⁸⁵ Articles 19 and 20 make post-release monitoring a required part of any written consent to a release of a product to market, with the effect that monitoring of the GM organism by the notifier is required.⁸⁶ The importance of this post-release monitoring requirement is enhanced by the fact that written consent to the placing of a GM product on the market can now only be given for a maximum of ten years, after which time an application to renew consent must be filed.⁸⁷ This

⁸² Council Directive 90/220, art. 16, 1990 Official Journal of the European Communities L117 of 08/05/1990, pp. 20

⁸³ Directive 2001/18 of the European Parliament and of the Council, art. 23, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 13.

⁸⁴ *Id.*

⁸⁵ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 240.

⁸⁶ Brian Sheridan, EU Biotechnology Law & Practice, (Palladian Law Publishing Ltd. 2001), pp. 30.

⁸⁷ Directive 2001/18 of the European Parliament and of the Council, art. 15, 17, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 10-11.

application to renew consent must include a report on the results of the post-release monitoring.⁸⁸

The requirement to seek renewed consent also applies to the eighteen GM products that had already secured approval under the prior Directive 90/220.⁸⁹ The addition of a process to renew consent essentially means the regulatory process with respect to GM organisms put on the market may continue indefinitely. Though an application for renewal of consent must be filed, the products may remain on the market pending renewal.⁹⁰ Taken together, the more extensive environmental risk assessment, the mandate of post-release monitoring, and the time-limited nature of any written consent a product ultimately receives demonstrate a notable increase in the stringency of the regulations applied to GM organisms by Directive 2001/18.

Despite its introduction of the precautionary principle, greater transparency with respect to consumers, and an increase in the stringency of the regulatory framework, Directive 2001/18 can hardly be considered a success. The same member states who had successfully pressed for the de facto moratorium on approvals of new GM products showed no signs of lifting the moratorium.⁹¹ As a consequence, the Commission went back to the drawing board to further modify the regulatory framework governing GM products.⁹² Regulation 1829/2003 EC on GM food and feed and Regulation 1830/2003 EC on the traceability and labeling of GM organisms and GM food and feed were passed in September 2003.⁹³ The provisions of these regulations replaced those of Directive 2001/18 with respect to the incorporation of GM organisms in food and feed and with respect to labeling and traceability, effectively making Directive 2001/18 apply only with respect to regulation of the deliberate release of GM organisms into the

⁸⁸ Directive 2001/18 of the European Parliament and of the Council, art. 17, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 11.

⁸⁹ *Id.*

⁹⁰ Brian Sheridan, *EU Biotechnology Law & Practice*, (Palladian Law Publishing Ltd. 2001), pp. 49.

⁹¹ Mark A. Pollack and Gregory C. Shaffer, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*, (Oxford University Press, 2009), pp 240.

⁹² *Id.*

⁹³ *Id.*

environment.⁹⁴ In reality, when a party makes an application for a food or feed product containing GM organisms, it has a choice of proceeding entirely under Regulation 1829/2003, or submitting its application under both Regulation 1829/2003 and Directive 2001/18.⁹⁵ As of the last update (on January 17, 2006) to the EU's list of authorized products under Directive 2001/18, there had been four consents to the marketing of GM products – these consents were given in 2004 and 2005 and covered three varieties of maize and one variety of oil seed rape, with authorized uses consisting mainly of import and use in feed and industrial processing.⁹⁶

Regulation 1829/2003 and Regulation 1830/2003

Regulation 1829/2003 EC governs the admission of GM food and feed products to the market. The regulatory structure created by Regulation 1829/2003 is broadly similar to that under Directive 2001/18 and Regulation 258/97, but with some important changes noted below. Food is defined by reference to Regulation 178/2002 EC to mean any substance or product intended or reasonably expected to be ingested by humans, while feed is defined to include any substance or product intended to be used for oral feeding to animals.⁹⁷ The definition of “genetically modified” is left unchanged from Directive 2001/18, which means that the process of genetic modification continues to mandate differential regulatory treatment as compared to non-GM goods regardless of the nature of the resulting GM product.⁹⁸ GM food and feed are defined to include food and feed containing, consisting of, or produced from (but not containing)

⁹⁴ *Id.*

⁹⁵ “Questions and Answers on the Regulation of GMOs in the European Union,” found at: http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.pdf, last accessed on March 25, 2010.

⁹⁶ “GMOs Authorised for Feed Use in the European Union in Accordance with Directives 90/220/EEC and 2001/18/EC,” found at: http://ec.europa.eu/food/food/biotechnology/authorisation/2001-18-ec_authorised_en.pdf, last accessed on March 25, 2010.

⁹⁷ Regulation 178/2002 of the European Parliament and of the Council, art. 2-3, 2002 Official Journal of the European Communities L31 of 02/01/2002, pp. 7.

⁹⁸ Regulation 1829/2003 of the European Parliament and of the Council, art. 2, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 6.

GM organisms.⁹⁹ Food or feed should be considered “produced from” GM organisms if “material derived from the genetically modified source material is present” in the product.¹⁰⁰ The scope of Regulation 1829/2003 covers all of the products previously covered by Directive 2001/18 (products that contain or consist of GM organisms) and the products previously covered by Regulation 258/97 (food and food ingredients that contain, consist of or are produced from GM organisms). Regulation 1829/2003 also makes it so that, for the first time, feed that is produced from GM organisms will be subjected to the GM product regulatory regime.¹⁰¹

As a consequence of the scope of the products it regulates, Regulation 1829/2003 effectively displaced certain provisions of Regulation 258/97 and Directive 2001/18. Regulation 1829/2003 explicitly amends Regulation 258/97 such that Regulation 258/97 no longer governs the placing on the market of food and food ingredients consisting of, containing or produced from GM products.¹⁰² Regulation 258/97 continued to be relevant for a time because certain of the applications made under it were still pending and would be considered under its provisions.¹⁰³ Although most of Directive 2001/18 was not explicitly amended by Regulation 1829/2003, the need to obtain approval under either Article 5 (for food) or Article 17 (for feed) of Regulation 1829/2003 has meant that Regulation 1829/2003 provides the operative provisions that must be complied with to get GM food or feed products on the market. Products which were previously approved under Directive 90/220 or Regulation 258/97 can stay on the market, so long as a notification is made to the Commission and a renewal application is made within three

⁹⁹ *Id.*

¹⁰⁰ Regulation 1829/2003 of the European Parliament and of the Council, whereas clause (16), art. 2, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 2, 6.

¹⁰¹ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, Oxford University Press, 2009, pp 241.

¹⁰² Regulation 1829/2003 of the European Parliament and of the Council, art. 38, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 19.

¹⁰³ Simonetta Zarelli, International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks, (Policy Issues in International Trade and Commodities Study Series No. 29, UNCTAD, United Nations Publication 2005), pp 11.

to nine years.¹⁰⁴ In displacing these other EU regulatory regimes, Regulation 1829/2003 establishes a more unified regulatory structure, which consolidates at least some of the duplicative regulatory schemes that had arisen over the past 13 years with respect to regulation of GM organisms. The movement towards a more unified regulatory structure is also reflected in the fact that under Article 27, if a product is likely to be used as both food or feed, a single application must be submitted under both Articles 5 and 17 and this application gives rise to a single authorization decision either approving of both food and feed uses, or refusing to approve the product.¹⁰⁵ This more unified approach to regulation of GM products has been termed an application of a “one door-one key” principle.¹⁰⁶

In creating a more unified regulatory approach with respect to GM products, Regulation 1829/2003 often adopts the most restrictive rules from the regulatory structures that it unifies. The substantive requirements of Articles 4 (with respect to food) and 16 (with respect to feed) are a prime example. Article 4 essentially carries over the substantive requirements from Regulation 258/97 that GM food products must not harm or mislead the consumer or cause nutritional disadvantages compared to the food products they are intended to replace, but extends them further by also barring harm to animal health and the environment.¹⁰⁷ Article 16 applies these same substantive requirements to feed products, along with an additional requirement that these products must not harm or mislead the customer by impairing distinctive features of animal

¹⁰⁴ Regulation 1829/2003 of the European Parliament and of the Council, art. 8, 20, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 9-10, 15

¹⁰⁵ Regulation 1829/2003 of the European Parliament and of the Council, art. 27, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 17; *See also* Bernd van der Meulen and Menno van der Velde, Food Safety Law in the European Union: An Introduction, (Wageningen Academic Publishers 2004), pp 181.

¹⁰⁶ Bernd van der Meulen and Menno van der Velde, Food Safety Law in the European Union: An Introduction, (Wageningen Academic Publishers 2004), pp 181.

¹⁰⁷ Regulation 1829/2003 of the European Parliament and of the Council, art. 4, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 7.

products.¹⁰⁸ Regulation 1829/2003 thus takes the more restrictive approach from the two prior regulatory regimes (applying substantive requirements directly to the products rather than relying on the application procedure) and applies this approach generally to all the categories of products that it covers, with the result that the regulatory burden on GM products increases overall. The same phenomenon can be seen in the abandonment of the substantial equivalence notification procedure for bringing GM products to market, jettisoning the more permissive approach of Regulation 258/97 in favor of the mandatory application procedure of Directives 90/220 and 2001/18.¹⁰⁹ In certain respects then, Regulation 1829/2003 achieves regulatory convergence by approximating and extending the most stringent of the rules under the previous regulatory frameworks.

The labeling requirements set out by Regulation 1829/2003 also demonstrate a process of regulatory convergence that results in a greater overall regulatory burden. As under both Directive 2001/18 and Regulation 258/97, if a product contains or consists of GM organisms, the label must clearly disclose this fact.¹¹⁰ In addition, as under Regulation 258/97, the label must explain differences from any conventional counterparts and also any possible ethical or religious concerns.¹¹¹ Rather than stopping at effectively combining the previous labeling requirements though, Regulation 1829/2003 went still further in making these labeling requirements applicable to products that had merely been produced from (but no longer contained) GM organisms.¹¹² These products must be labeled with a statement that they contain ingredients produced from

¹⁰⁸ Regulation 1829/2003 of the European Parliament and of the Council, art. 16, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 12

¹⁰⁹ Regulation 1829/2003 of the European Parliament and of the Council, whereas clause (6), 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 1.

¹¹⁰ Regulation 1829/2003 of the European Parliament and of the Council, art. 13, 25, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 11-12, 17.

¹¹¹ *Id.*

¹¹² Regulation 1829/2003 of the European Parliament and of the Council, art. 12, 24, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 11, 16.

GM organisms.¹¹³ Regulation 1829/2003 also established a minimum threshold for required labeling (a concept which had been contemplated by Directive 2001/18 but never implemented) at the level of 0.9% of the food ingredients, provided these materials' presence was adventitious or technically unavoidable.¹¹⁴ One might think that the establishment of a fixed threshold would weaken the regulatory requirements for labeling. Nevertheless, the fact that products with ingredients produced from GM organisms must be labeled means that a much greater number of products, even those that are highly processed, are now subject to the labeling regime.¹¹⁵ In combination with the traceability requirements of Regulation 1830/2003 that help police this minimum threshold, the increased stringency of the labeling regime under Regulation 1829/2003 reveals the continued trend in EU regulation towards giving greater protection to consumers' right to know when they are consuming GM products.

Regulation 1830/2003 EC, which establishes the rules governing the traceability of food and feed products containing, consisting or produced from GM organisms, came into effect in April 2004, along with Regulation 1829/2003.¹¹⁶ Traceability means the "ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains."¹¹⁷ Article 8 provides that a system shall be set up to assign a unique identifier to each GM organism or product.¹¹⁸ At each point in the production or distribution chain, the seller must provide to the buyer (so long as the buyer is not the final

¹¹³ Regulation 1829/2003 of the European Parliament and of the Council, art. 13, 25, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 11-12, 17.

¹¹⁴ Regulation 1829/2003 of the European Parliament and of the Council, art. 12, 24, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 11, 16.

¹¹⁵ See Bernd van der Meulen and Menno van der Velde, Food Safety Law in the European Union: An Introduction, (Wageningen Academic Publishers), 2004, pp 198-199.

¹¹⁶ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 240.

¹¹⁷ Regulation 1830/2003 of the European Parliament and of the Council, art. 3, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 25.

¹¹⁸ Regulation 1830/2003 of the European Parliament and of the Council, art. 8, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 27.

consumer) information about the GM contents of the food or feed product.¹¹⁹ Each of the buyers and sellers is required, for a period of five years, to hold information on the GM contents of these products “one step backward and one step forward” in the production or distribution chain.¹²⁰ Traceability provisions facilitate surveillance of and, if necessary, withdrawal from the market of GM products, and they also help the regulatory authorities to enforce labeling obligations established under other regulations and directives.¹²¹ Regulation 1830/2003 may be seen as further centralizing the rules on tracing and labeling, as opposed to Directive 2001/18 which had placed more power over labeling and tracing with the individual member states.¹²² Regulation 1830/2003 increased the regulatory burden on producers and distributors of GM products and enhanced the importance of EU-level rules and institutions at the expense of those of the individual member states.

Regulation 1829/2003 modifies the approval procedures for bringing a product to market that existed under the prior regulatory regimes, and in so doing strengthens the power and regulatory authority of the EU-level institutions, particularly the Commission, at the expense of the member states. Just as under the old rules, the application process begins when an applicant submits an application to the competent authority of a member state. As described earlier, Directive 2001/18 allowed the member state which received the application to reject the application and Regulation 258/97 permitted the member state receiving the application to at least make an initial assessment of whether the application should be approved. Regulation 1829/2003 strips these functions from the member state to which an initial application is made –

¹¹⁹ Regulation 1830/2003 of the European Parliament and of the Council, art. 4-5, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 26-27.

¹²⁰ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 244.

¹²¹ Brian Sheridan, EU Biotechnology Law & Practice, (Palladian Law Publishing Ltd. 2001), pp. 189.

¹²² Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 244.

the sole function of the initial recipient member state is to pass along the application to the European Food Safety Board (EFSA), an EU institution.¹²³ The initial recipient member state's function has been reduced to that of a "box office" for the submission of applications, though these member states may still participate equally with other member states in the subsequent decision-making process.¹²⁴ After receiving an application, the EFSA prepares an opinion as to whether the food or feed product should be allowed on the market, taking care to consider whether the required information under either Article 5 or 17 has been submitted and whether the substantive requirements of Article 4 or 16 have been met.¹²⁵ The Commission receives the EFSA opinion and then prepares a draft decision, which may differ from the EFSA opinion but must explain such differences.¹²⁶ EFSA and the Commission's increased power over the initial decision whether to approve a product comes at the direct expense of the member states which are no longer able to reject an application or even prepare an initial opinion.

Regulation 1829/2003 considerably expands the factors that may be considered by the Commission in making its draft decision. The Commission may consider all "other legitimate factors relevant to the matter."¹²⁷ Taken together with Article 1's expansion of regulatory objectives to explicitly include protection of "consumer interests," the Commission has a great deal of discretion in making its initial decision.¹²⁸ After the Commission makes its initial draft decision, Regulation 1829/2003 applies the same basic Commission-Committee-Council

¹²³ Regulation 1829/2003 of the European Parliament and of the Council, art. 5, 17, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 7, 13

¹²⁴ Bernd van der Meulen and Menno van der Velde, Food Safety Law in the European Union: An Introduction, (Wageningen Academic Publishers 2004), pp 181.

¹²⁵ Regulation 1829/2003 of the European Parliament and of the Council, art. 6, 18, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 8, 14

¹²⁶ Regulation 1829/2003 of the European Parliament and of the Council, art. 7, 19, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 9, 14.

¹²⁷ *Id.*

¹²⁸ Regulation 1829/2003 of the European Parliament and of the Council, art. 1, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 5; *See also* Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, (Oxford University Press 2009), pp 241.

decision-making procedure that existed under Directive 2001/18.¹²⁹ It will be recalled that under this procedure, in the event of an objection by the committee, the Commission's initial decision enters into force if the Council is unable to reach agreement by a qualified majority. In sum, Regulation 1829/2003 expands the Commission's power over the initial approval decision, increases the Commission's discretion in the making of this initial decision, and preserves the ability of the Commission to make its decision law in the event the Council becomes deadlocked. Regulation 1829/2003 may therefore be seen as consolidating and strengthening the Commission's role as the regulatory actor with the most control over whether an application will be approved or rejected.

Regulation 1829/2003 also enhances the regulatory authority of EU level institutions at the expense of the member states by subjecting member states' exercise of emergency measures (previously known as safeguards) to further regulatory discipline. Under the rules of Directive 2001/18 and Regulation 258/97, a member state could implement a safeguard and only afterwards would have to inform the Commission and justify its decision.¹³⁰ Tracing the history of the safeguard clauses from Directive 90/220 on, we saw earlier that the trend in regulation heretofore had been to require the member states to make more detailed justifications of their safeguard decisions. Article 34 of Regulation 1829/2003 goes further and makes Articles 53 and 54 of Regulation 178/2002 applicable to emergency measures with respect to GM products.¹³¹ A member state that desires the imposition of an emergency measure must first request that the Commission act and give the Commission an opportunity to impose its own emergency measures

¹²⁹ Regulation 1829/2003 of the European Parliament and of the Council, art. 35, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 19.

¹³⁰ Directive 2001/18 of the European Parliament and Council, art. 23, 2001 Official Journal of the European Communities L106 of 04/17/2001, pp. 13; Regulation 258/97 of the European Parliament and of the Council, art. 12, 1997 Official Journal of the European Communities L43 of 02/14/1997, pp. 6

¹³¹ Regulation 1829/2003 of the European Parliament and of the Council, art. 34, 2003 Official Journal of the European Union L268 of 10/18/2003, pp. 19.

(the Commission may also act on its own initiative).¹³² The member state may only impose an emergency measure if the Commission has not acted within 10 days after the notification.¹³³ The new provisions on emergency measures enhance the power of the Commission, giving it the authority to impose these measures on its own authority or at the request of member states. Having been introduced into the safeguard process at an earlier stage, the Commission may be able to shape the regulatory outcome as it decides from a range of potential emergency measures. The member states see their authority limited to an extent as they can no longer act first and justify later. The changes to the safeguard clauses from the earlier regulatory regimes further reinforce one of the overarching themes of Regulation 1829/2003 – the shift of ever greater regulatory power and decision-making discretion from member states to EU institutions.

After the adoption of Regulation 1829/2003 and Regulation 1830/2003, the approval of the market introduction of GM products resumed. Though some countries remained hostile to GM products, the Commission could approve these products for market because the Council could not reach decisions on approval by the required qualified majority vote.¹³⁴ From May 2004 to November 2008, each case involving approval of a GM product resulted in a deadlock in the committee, which meant the Commission's draft decision went to the Council, where a "pattern of deadlock" persisted.¹³⁵ Seventeen GM products were approved under Regulation 1829/2003 between May 2004 and November 2008.¹³⁶ The EU's Community Register of GM food and feed shows thirty-two products are currently authorized for use in the EU, though the

¹³² Regulation 178/2002 of the European Parliament and of the Council, art. 53, 2002 Official Journal of the European Communities L31 of 02/01/2002, pp. 22.

¹³³ Regulation 178/2002 of the European Parliament and of the Council, art. 54, 2002 Official Journal of the European Communities L31 of 02/01/2002, pp. 22.

¹³⁴ Mark A. Pollack and Gregory C. Shaffer, When Cooperation Fails: The International Law and Politics of Genetically Modified Foods, Oxford University Press, 2009, pp 244-247, 253-255.

¹³⁵ *Id.* at 246-247.

¹³⁶ *Id.* at 254.

renewal of authorization for many of these products is currently pending.¹³⁷ As a result of deadlock in the committee and the Council, the Commission found itself essentially in charge of these approval decisions. In practice, therefore, as would be expected based on regulatory structure, the Commission has become the main actor in the approval of GM products under Regulation 1829/2003.

Conclusion

Examination of the regulatory changes from the first steps towards regulating GM products in 1990 to the current GM regulatory system reveals a number of trends. Over time, the scope of GM products subject to regulation increased. As product scope increased, so too did the regulatory burden imposed on GM products – the required risk assessments became more detailed and post-market monitoring and labeling requirements became more intrusive. The earlier regulatory initiatives left a great deal of discretion to the member states in the approval procedures. As time went on, however, the interference created by recalcitrant member states made the approval procedure nigh inoperable. Centralization of regulatory authority at the EU level, particularly in the hands of the Commission, became necessary to make the GM regulatory system work for the entire European market. As the EU’s GM regulatory structure developed, justifications for its existence also found new expression. The precautionary principle became, explicitly, a central part of the regulatory process and the consumers’ right to know also took on greater importance as provisions for transparency were introduced. The broad outlines of the original GM regulatory structure from 1990 may still be seen in operation today, but the current GM regulations go much further than their forebears in centralizing authority, increasing

¹³⁷ “Community register of genetically modified food and feed,” found at: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm, last accessed March 25, 2010.

regulatory burdens on producers and distributors, and embracing new rationales for such increased regulatory burdens. Though controversial, the current system functions relatively well, allowing the Commission to decide whether to approve GM products for market while member states, more subject to popular anti-GM pressures, find their hands tied by the established decision-making procedures. In a common market made up of so many national polities, the current Commission-centered regulatory approach may be the most workable solution to the problems posed by regulation of GM products.